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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,519	09/22/2003	Andre Stamm	107664.115 US10	5826

26694 7590 12/04/2006

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/665,519	STAMM ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-84* is/are pending in the application.

4a) Of the above claim(s) *1-15,56-80,83 and 84* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-55,81 and 82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5/9/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election requirement and the request for extension of time (1 month-granted), all filed 09/06/06 is acknowledged. Receipt is also acknowledged of the Information Disclosure Statements (IDS) filed 9/22/03; 6/18/04; 6/28/04; 5/9/06; and 6/19/06. Acknowledgement is also made of the Terminal Disclaimers filed 05/02/06 and 6/19/06.

Applicant's election with traverse of Group II (Claims 16-55, 81 & 82) in the reply filed on 09/06/06 is acknowledged.

Claims 1-15, 56-80, 83 & 84 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 09/06/06.

Claims 1-84 are pending in this action. Claims 1-15, 56-80, 83 & 84 have been withdrawn. Claims 16-55, 81 & 82 are rejected.

Terminal Disclaimer

The terminal disclaimers filed on 05/02/06 and 06/19/06 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application Nos. 10/665,516; 10/665,517; 10/665,518; 10/665,520;

10/665,522 and 10/290,333 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The terminal disclaimers filed on 05/02/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent Nos. 6,652,881; 6,589,552; 6,596,317; 6,277,405; 6,074,670 and 7,037,529 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-25, 32-34, 36-45, 52-54, 81 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyer (US Pat. No. 4,800,079).

The instant invention is drawn to a fenofibrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate, inert carrier particles, at least one hydrophilic polymer and at least one disintegrant, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

Boyer ('079) teaches a fenofibrate composition comprising granules, wherein each granule comprises an inert core constituted with hydrosoluble carrier particles (lactose, sucrose, glucose), a hydrophilic polymer (polyvinylpyrrolidone) and a fenofibrate layer and a protective layer wherein the fenofibrate is in the form of crystalline microparticles having a particle size of not greater than 30 microns and preferably less than 10 microns (see abstract and reference columns 2-4). Starch (disintegrant) can also be included in the composition (Claims 3 & 7).

Boyer teaches fenofibrate granules wherein the inert matrix is composed by a binder selected from the group comprising: *methacrylic polymers, polyvinylpyrrolidone, mixtures thereof; cellulose derivatives; and polyethylene glycols* (claim 2). The inert core is constituted by a substance selected from the group comprising: *glucose, sucrose, lactose and their*

equivalents, starch and mixtures thereof (claim 3). The fenofibrate composition includes a protective coating layer, representing about 1% by weight of each granule and is formed of a substance selected from the group comprising: *methacrylic polymers, polyvinylpyrrolidone, mixtures thereof; cellulose derivatives; and polyethylene glycols* (claim 4). The amount of binder is such that the quantity of fenofibrate liberated in one hour in an aqueous liquid is not less than 65% (claim 5). The dimensions of the microparticles are *less than 10 microns* (claim 6).

Boyer teaches that the granules obtained are put into capsules with a dose of 250 mg of fenofibrate per capsule. Boyer teaches that the fenofibrate layer is similar to that of a sponge, with the pores containing microparticles of fenofibrate. A binder, methacrylate or polyvinylpyyrolidone, which is soluble in aqueous medium, constitutes the sponge. Once the binder has dissolved, the microparticles of fenofibrate are released. The amount of binder is determined so that at least 65% of the fenofibrate is released in one hour in a water-based liquid medium (col. 3, lines 10-45).

Boyer teaches that the inert grains for forming the inert cores can have a diameter adjusted from 0.3 mm (or 300 microns) to 0.6 mm (or 600 microns) (col. 2, lines 38-51).

In the Example at col. 3, fenofibrate is provided in amounts of 400 kg, inert grains (sugar and/or starch) are provided in amounts of 110 kg and polyvinylpyrrolidone and/or methacrylate are provided in amounts of 20 kg. Thus, the weight ratio of fenofibrate: polyvinylpyrrolidone and/or methacrylate is 20:1.

While Boyer does not explicitly teach the instantly claimed weight ratio of fenofibrate to hydrophilic polymer, nor the instant amounts of fenofibrate, carrier and hydrophilic polymer as

claimed in claims 32-33 & 52-53, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, Applicants have not demonstrated any superior or unexpected results, which accrue from the claimed weight ratios or amounts. The prior art recognizes and teaches similar formulations comprising similar ingredients, intended to treat the same problems as that desired by Applicants. No patentable distinction has been observed, which accrues from the instant amounts claimed since effective results are obtained using the compositions of Boyer.

With regards to instant claims 81 and 82, the granules of Boyer comprised of fenofibrate would be in non-reagglomerated form.

Given the explicit teachings of Boyer, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 16-55, 81 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtet *et al.* (US Pat. No. 4,895,726).

The instant invention is drawn to a fenofibrate composition comprising granulates, wherein the granulates comprise micronized fenofibrate, inert carrier particles, at least one

hydrophilic polymer and at least one disintegrant, wherein the weight ratio of micronized fenofibrate to hydrophilic polymer is between 1:10 and 4:1.

Curtet *et al.* ('726) teach a fenofibrate composition comprising fenofibrate granules in combination with a solid surfactant, wherein the fenofibrate and solid surfactant have been co-micronized; a hydrosoluble carrier and a hydrophilic polymer, wherein the fenofibrate/solid surfactant mixture granules have a mean particle size of less than 15 microns (see column 1, line 1 – col. 2, line 25); examples and claims.

Curtet *et al.* teach polyvinylpyrrolidone as the hydrophilic polymer employed. The hydrosoluble carrier taught is lactose (col. 2, lines 1-12). The preferred solid surfactant is sodium lauryl-sulfate in a recommended amount of between 0.5% and 7% (col. 1, lines 52-58). Excipients, such as magnesium stearate (lubricant) and starch (distintegrant) may also be added (col. 2, lines 1-4).

Curtet *et al.* teach a micronized fenofibrate composition containing a micronized mixture of particles of fenofibrate and a solid surfactant and method for preparing the fenofibrate composition comprising (i) intimately mixing and then co-micronizing the fenofibrate and the solid surfactant, (ii) adding lactose and starch to the mixture obtained, (iii) converting the whole to granules in the presence of water, (iv) drying the granules until they contain no more than 1% of water, (v) grading the granules, (vi) adding polyvinylpyrrolidone and magnesium stearate to the graded granules and (vii) filling gelatin capsules with the mixture obtained in stage (vi). The mean particle size of the micronized mixture obtained is less than 15 microns (μm) (column 2, lines 5-20).

Curtet *et al.* teach effective amounts of fenofibrate and a hydrophilic polymer-polyvinylpyrrolidone, wherein the fenofibrate is present in an amount of 200 mg per therapeutic unit (col. 1, lines 50-51) and the polyvinylpyrrolidone is contained in an amount of 7 mg (col. 3, lines 21-32).

While Curtet *et al.* do not explicitly teach the instantly claimed weight ratio of fenofibrate:hydrophilic polymer; surfactant:hydrophilic polymer, nor the instant amounts of fenofibrate and carrier as claimed in claims 32-33 & 52-53, the Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, Applicants have not demonstrated any superior or unexpected results, which accrue from the claimed weight ratios or amounts. The prior art vividly recognizes and teaches similar formulations comprising similar ingredients (fenofibrate, polymer, inert particles, etc.) that are used in the same field of endeavor to effectively treat the same problems (*i.e.*, hypercholesterolemia) as that desired by Applicants. No patentable distinction has been observed, which accrues from the instant amounts claimed since effective results are obtained using the compositions of Curtet *et al.*

Hence, given the explicit teachings of the art delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

HUMERA N SHEIKH
PRIMARY EXAMINER

Art Unit 1615

November 27, 2006

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